K042408

OCT 8 -- 2004

EXHIBIT 2

510(k) Summary

EDDA Technology, Inc
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Tel: 609-936-8282
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Contact: Xiaolan Zeng, Vice President, Clinical Affairs
Date: August 30, 2004

1. Identification of the Device:
   Proprietary-Trade Name: IQQA-Chest Software Package
   Classification Name: System, Image Processing, Radiological, Product Code 90 LLZ
   Common/Usual Name: Radiological Image Processing System

2. Equivalent legally marketed devices:

Manufacturer	Name of the Predicate Device	FDA 510(k) Number	FDA Clearance Date
Siemens Medical Systems	LungCARE CT Software Package with extended functionality	K033374	11/06/2003
R2 Technology	ImageChecker CT software package with Filling Defect Indicator	K041380	06/08/2004

3. Indications for Use (intended use): The IQQA-Chest is a PC-Based, self-contained, non-invasive image analysis package used during the review of digital chest radiographic images. Combining image viewing, evaluation and reporting tools, the software is designed to support the physician in the identification of lung lesions (e.g. nodules), as well as the confirmation, evaluation and documentation of such physician-identified lesions. The IQQA-Chest software package supports a workflow based on automated segmentation for the visual identification of possible lesions. The tools also allow for regional analysis of possible lesions in terms of size, shape and position, thus aiding the physician in the characterization of physician-identified suspicious lesions. Image source: DICOM

4. Description of the device: The IQQA-Chest Software Package is a self-contained, non-invasive thoracic radiographic image analysis package that is designed to run on standard PC hardware. Combining image viewing tools (e.g. image window level, pan, zoom, enhancement viewing), evaluation tools (e.g. automatic/interactive segmentation, quantitative measurements derived from marking and segmentation), and reporting tools (e.g. saved lesion location, measurement information, physician-

input nodule characterization, and etc), the software package is designed to support the physician in the identification of lung lesions (e.g. nodules), as well as the confirmation, evaluation and documentation of such physician-identified lesions. The IQQA-Chest software package supports a workflow based on automated segmentation for the visual identification of possible lesions (nodule enhanced viewing). Based on physician's request, the tool segments locations in the lung area containing circular densities (connected pixels fulfilling intensity signal and circular shape constraints) that would typically correlate with lung nodules. The tools also allow for regional analysis of possible lesions with respect to size, shape and position, aiding the physician in the characterization of physician-identified suspicious lesions.

5. Safety and Effectiveness, comparison to predicate device:

	Predicate Device: **Siemens LungCARE CT software package with extended functionality (K033374)**	*Predicate Device:* **R2 ImageChecker CT Software Package with Filling Defect Indicator (K041380)**	*Device of 510(k) submission:* **IQQA-Chest Software Package**
Manufacturer	Siemens Medical Solutions	R2 Technology, Inc	EDDA Technology, Inc.
Indications for Use	LungCARE CT is a self-contained image analysis software package for evaluating CT volume data sets. Combining enhanced commercially available digital image processing tools with an optimized workflow and reporting tools, the software is designed to support the physician in confirming the presence or absence of physician identified lung lesions (e.g. nodules) in addition to evaluation, documentation and follow-up of any such lesions using standard or low-dose spiral CT scanning. The LungCARE CT Software Package with extended functionality contains modifications which support the user with a special workflow based on automated segmentation for the visual identification of possible lesions (Nodule Enhanced Viewing). This visualization tool allows for volumetric analysis of pulmonary nodule or lesion size over time, helping the Physician to assess the changes in their growth. It is also designed to	The ImageChecker CT Software Package with Filling Defect Indicator (FDI) is used during the review of contrast-enhanced CT images of the chest. This software tool enables the radiologist to view and analyze regions of the image containing low density within vascular structures that may be indicative of filling defects or other intravascular abnormalities. The software is designed to assist the radiologist in characterization and classification of these suspicious candidate thoracic abnormalities in terms of density, size, dimension, shape and position, thus aiding in the patient management care decision process.	The IQQA-Chest is a PC-Based, self-contained, non-invasive image analysis package used during the review of digital chest radiographic images. Combining image viewing, evaluation and reporting tools, the software is designed to support the physician in the identification of lung lesions (e.g. nodules), as well as the confirmation, evaluation and documentation of such physician-identified lesions. The IQQA-Chest software package supports a workflow based on automated segmentation for the visual identification of possible lesions. The tools also allow for regional analysis of possible lesions in terms of size, shape and position, thus aiding the physician in the characterization of physician-identified suspicious lesions. Image source: DICOM

	Predicate Device: **Siemens LungCARE CT software package with extended functionality (K033374)**	*Predicate Device:* **R2 ImageChecker CT Software Package with Filling Defect Indicator (K041380)**	*Device of 510(k) submission:* **IQQA-Chest Software Package**
	help the physician classify conspicuous regions of tissue unambiguously having determined their size, dimensions, shape and position.		
Hardware / Operating systems	Standard PC / Windows	Standard PC / Windows	SAME
User interface	A graphical user interface for users to interact with the software, select tools and drive workflow	A graphical user interface for users to interact with the software, select tools and drive workflow	SAME

6. Testing information and Conclusion
   In all material respects, the IQQA-Chest Software Package is substantially equivalent to the predicate systems. Testing was performed according to internal company procedures. Software testing and validation were done according to written test protocols established before testing was conducted. Test results were reviewed by designated technical professionals before software proceeded to release. Test results support the conclusion that actual device performance satisfies the design intent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 8 - 2004

EDDA Technology, Inc.
% Daniel Kamm, P.E.
Regulatory Engineer
Kamm & Associates
PO Box 7007
DEERFIELD IL 60015

Re: K042408
Trade/Device Name: IQQA-Chest
Software Package
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and
communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: August 30, 2004
Received: September 3, 2004

Dear Mr. Kamm:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K042408

Device Name: IQQA-Chest Software Package

The IQQA-Chest is a PC-Based, self-contained, non-invasive image analysis package used during the review of digital chest radiographic images. Combining image viewing, evaluation and reporting tools, the software is designed to support the physician in the identification of lung lesions (e.g. nodules), as well as the confirmation, evaluation and documentation of such physician-identified lesions.

The IQQA-Chest software package supports a workflow based on automated segmentation for the visual identification of possible lesions. The tools also allow for regional analysis of possible lesions in terms of size, shape and position, thus aiding the physician in the characterization of physician-identified suspicious lesions. Image source: DICOM

Prescription Use X ~~AND~~/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David G. Seguin

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K042408